December 6, 2022

Siemens Medical Solutions USA, Inc.
% Patricia Jones
Regulatory Affairs Professional
40 Liberty Boulevard
MALVERN PA 19355

Re: K223409
Trade/Device Name: Cios Select (VA21) Image Intensifier
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, JAA
Dated: November 4, 2022
Received: November 9, 2022

Dear Ms. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang 2022.12.06 19:31:17 -05'00'

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223409

Device Name
Cios Select (VA21) Image Intensifier

Indications for Use *(Describe)*

The Cios Select is a mobile X-ray system intended for use in Operating room, Traumatology, Endoscopy, Intensive Care Station, Pediatrics, Ambulatory patient care and in Veterinary Medicine.

The Cios Select can operate in four different modes, Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy and Cassette exposure which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of an intra-medullary nail implants in various positions, low dose fluoroscopy in pediatrics, fluoroscopic techniques utilized in pain therapy and positioning of catheters and probes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: Cios Select (VA21) Image Intensifier
Submission Number: K223409

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Date Prepared: December 5, 2022

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. **General Information:**

   Importer / Distributor:
   Siemens Medical Systems USA, Inc.
   40 Liberty Boulevard
   Malvern, PA 19355
   Establishment Registration Number: 2240869

   Manufacturing Site:
   Siemens Shanghai Medical Equipment Ltd.
   278 Zhou Zhu Road, Shanghai
   201318, China
   Establishment Registration Number: 3003202425

2. **Contact Person:**

   Patricia D. Jones
   Regulatory Affairs Specialist
   Siemens Medical Solutions USA, Inc.
   40 Liberty Boulevard
   Malvern, PA 19355
   Phone: (678) 575-8832
   Email: patricia.jones@siemens-healthineers.com

3. **Device Name and Classification:**

Trade Name:	**Cios Select (VA21) Image Intensifier**
Classification Name:	Image-Intensified Fluoroscopic x-ray System
Classification Panel:	Radiology
Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Codes:	OWB, OXO, JAA

4. **Legally Marketed Predicate Device**

Trade Name:	**Cios Select (VA21) Image Intensifier**
510(k) Clearance	K210307
Clearance Date	March 4, 2021
Classification Name:	Image-intensified fluoroscopic x-ray System
Classification Panel:	Radiology

Regulation Number:	21 CFR §892.1650
Device Class:	Class II
Product Code:	OWB
Subsequent Product Codes:	JAA, OXO
Total Product Life Cycle:	There are no Recalls nor MDR incidents for this cleared device.

5. Device Description:

Theis 510(k) submission, Cios Select (VA21C) with Imagine Intensifier is a Mobile C-arm X-ray System, which is a modification of the Cios Select (VA21) Image Intensifier originally cleared under Premarket Notification K210307 on March 04, 2021.

The Cios Select consists of two major units:

One is the acquisition unit with the C-arm and movable base containing the generator, power unit, system control, and tube housing assembly on one side of the C-arm and the image intensifier on the opposite side.

The second unit is the image display station with a moveable trolley for the image processing and storage system, image display, and documentation. Both units are connected to each other with a cable. The main unit is connected to the main power outlet and the trolley is connected to a data network.

The following modifications were made to the Predicate Device the Cios Select Mobile X-ray System cleared under Premarket Notification K210307 on March 04, 2021. Siemens Medical Solutions USA, Inc. submits this Special 510(k) to request clearance for the Subject Device the Cios Select (VA21C) with Imagine Intensifier. The following minor modifications are incorporated in the Predicate Device to create the Subject Device, for which Siemens is seeking 510(k) clearance:

1. Updated Software from VA21B to VA21C to support the following hardware changes.
   a. New collimator
   b. New PC hardware (Mini PC)
   c. Replaced Camera in Image Intensifier
2. Updated 510(k) Information

6. Indications for Use:

The Cios Select is a mobile X-ray system intended for use in Operating room, Traumatology, Endoscopy, Intensive Care Station, Pediatrics, Ambulatory patient care and in Veterinary Medicine.

The Cios Select can operate in four different modes, Digital Radiography, Fluoroscopy, and Pulsed Fluoroscopy and Cassette exposure which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of an intra-medullary nail implants in various positions,

low dose fluoroscopy in pediatrics, fluoroscopic techniques utilized in pain therapy and positioning of catheters and probes.

7. Substantial Equivalence:

The Cios Select (VA21C) with Imagine Intensifier system is within the same classification regulation with the same indications for use as the legally marketed predicates listed in **Table 1.** below:

Table 1: Predicate Device Comparable Properties for Subject Device Modifications:

Predicate Device Name and Manufacturer	510(k) Number	Clearance Date	Comparable Properties
Predicate Device	K210307	3/4/2021	• Indications for use • X-ray technology • Image processing • Mechanical design • Cybersecurity • Software • Collimator • PC Hardware
Cios Select (VA21) Image Intensifier Siemens Shanghai Medical Equipment Ltd.			

8. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

The Indications for Use Statement is exactly the same as the cleared Predicate Device “Cios Select (VA21) Image Intensifier, K210307”.

The Cios Select (VA21) with system software version VA21C contains the following minor modifications that were made to the predicate device. Provided in **Table 2** is a summary of the comparison of Technological Characteristics to the Predicate Device.

Table 2: Summary of Comparison of Technological Characteristics

Modifications	Subject Device Cios Select (VA21C) with Image Intensifier	Predicate Device Cios Select (VA21B) Image Intensifier K210307	Comparable Properties
1. Software	Updated Software to VA21(C)	VA21(B)	**Modified:** Update the software from VA21(B) to VA21(C) to support the following hardware change, no new software features are included in this software version.
a. Collimator	New Collimator	Collimator	**Comparable:** The new collimator has the same functionality as cleared in the Predicate Device **Cios Select (VA21) Image Intensifier K210307** and does not raise any new or effectiveness issues.
b. PC hardware	New Mini-PC	W550 PC	**Comparable:** The new mini-PC has the same functionality as cleared in the Predicate Device **Cios Select (VA21) Image Intensifier K210307** and does not raise any new or effectiveness issues.
c. Image Intensifier	Updated Camera in Image Intensifier	Image Intensifier	**Comparable:** The only major change from the predicate device is the upgrade of the image intensifier camera. The camera has been updated to CMOS technology (from CCD in the predicate fluoro system). Testing for image quality has been performed and test results indicate substantial equivalence for this image intensifier component. The new camera within Image Intensifier has the same functionality as cleared in the Predicate Device Cios Select VA21 Image Intensifier K210307 and does not raise any new or effectiveness issues.

9. Nonclinical Performance Testing:

Non-clinical tests were conducted for the Cios Select (VA21C) with Imagine Intensifier during product development. The Siemens Cios Select (VA21C) Imagine Intensifier has been tested to meet the requirements for conformity to multiple industry standards. Performance testing confirmed, that the Siemens Cios Select (VA21C) Imagine Intensifier complies with the following 21 CFR Federal Performance Standards

Code of Federal Regulations Title 21 Subchapter J- Radiological Health, applicable sections include:

- 1020.30 Diagnostic X-Ray System and their major component
- 1020.31(h)(2)(3) Alignment of the X-ray field and spot-film cassette
- 1020.32 Fluoroscopic Equipment
- 1040.10 Laser products

The Cios Select (VA21C) with Imagine Intensifier was certified by Siemens Healthcare GmbH Corporate Testing Laboratory to comply with the following standards for Electrical safety, performance and Electromagnetic Compatibility:

- AAMI ANSI ES60601-1:2005/(R)2012
- IEC 60601-1-2:2014
- IEC 60601-1-3:2013
- IEC 60601-1-6:2010/A1:2013
- IEC 60825-1:2014
- IEC 62304:2015

- IEC 60601-2-28:2017
- IEC 60601-2-43:2019
- IEC 60601-2-54:2018
- IEC 62366-1:2015
- ISO 14971:2019

The modifications described in this Premarket Notification are supported with verification and validation testing.

Verification and Validation:
Software Documentation for a **Moderate** Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, and "Off-The-Shelf Software Use in Medical Devices" is also included as part of this submission. The performance data demonstrate continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on the Subject Device Cios Select with Image Intensifier software version VA21C during product development. The device software is based on the predicate software package and no major changes were performed on the software.

The Risk analysis was completed, and risk control was implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

Bench testing in the form of Unit, Subsystem, and System Integration testing was performed to evaluate the performance and functionality of the new features, hardware, and software updates. All testable requirements in the Engineering Requirements Specifications keys, Subsystem Requirements Specifications keys, and the Risk Management Hazard keys have been successfully verified and traced in accordance with the Siemens product development (lifecycle) process. The software verification and regression testing have been performed successfully to meet their previously determined acceptance criteria as stated in the test plans.

Electrical safety and EMC testing were conducted on the Cios Select, consisting of the acquisition unit (C-arm system) and the image processing and display station. The system complies with the IEC 60601-1, IEC 60601- 2-43, and IEC 60601-2-54 standards for safety and the IEC 60601-1-2 standard for EMC.

The Cios Select with Image Intensifier software (VA21C) was tested and found to be safe and effective for intended users, uses, and use environments through the design control verification and validation process. The Human Factor Usability Validation showed that Human factors are addressed in the system test according to the operator's manual and in clinical use tests with customer reports and feedback forms. Customer employees are adequately trained in the use of this equipment.

Siemens conforms to the cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse, or denial of use, or the unauthorized use of information that is stored, accessed or transferred from a medical device to an external recipient. Provided in this submission is a cybersecurity statement that considers IEC 80001-1:2010. The responsibility for compliance with IEC 80001-1-2010 is the hospital. Provided in the Software Section is the required cybersecurity information.

Summary:
Performance tests were conducted to test the functionality of the Cios Select (VA21C). These tests have been performed to assess the functionality of the Subject Device. The results of all conducted testing and clinical assessments were found acceptable and do not raise any new issues of safety or effectiveness. Clinical testing is not necessary, based on the changes to the predicate device. Successful Bench Testing results should be sufficient in showing that the Cios Select fluoro system is safe and effective for use.

10. General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Risk management is ensured via a hazard analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification, and validation testing. To minimize electrical and mechanical hazards, Siemens adheres to recognized and established industry practices, and all equipment is subject to final performance testing. Furthermore, the operators are healthcare professionals familiar with and responsible for the evaluation and post-processing of X-ray images.

11. Conclusion as to Substantial Equivalence:

The predicate devices were cleared based on non-clinical supportive information and clinical images and data. Similar non-clinical test results demonstrate that the Cios Select (VA21C) with Imagine Intensifier System acceptance criteria is adequate for the intended use of the device. The comparison of technological characteristics, non-clinical performance data, and software validation data demonstrates that the Subject Device is as safe and effective when compared to the Predicate Devices that is currently marketed for the same intended use.